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Virginia Board of Pharmacy

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Board Member Appointments

Virginia Board of Pharmacy members are appointed by the governor for a four year term, not to exceed two full terms. It is certainly an honor to be recognized, and the profession of pharmacy is fortunate to consistently have dedicated individuals appointed who give their time to attend Board meetings, committee meetings, and disciplinary hearings with very little financial compensation in return. During the last year, the governor appointed or reappointed several individuals to the Board.

In December 2005, Michelle Easton relocated to West Virginia and was no longer eligible to serve as a Board member. Her first term was set to expire June 30, 2006, and the governor appointed Michael E. Stredler in January 2006 to finish this term. Mr Stredler was then reappointed to his first full term in June 2006. Additionally, in June 2006, the governor reappointed for a second term Leo H. Ross, Bobby Ison, and Willie Brown. Appointed for their first terms are Jennifer H. Edwards and Brandon K. Yi, who replaced Mark A. Oley and Toni Aust. Mr Oley had completed his second term and was ineligible for reappointment. Ms Aust resigned her Board member position when accepting a staff position with the Virginia Department of Health Professions as a pharmacy inspector. Additional Board members who are currently in their first term are John O. Beckner, Gill B. Abernathy, David C. Kozera, and Diane M. Langhorst.

The Board chairman is elected by the Board members for a one-year term. In June 2006, Mr Ross completed his term as chairman, and Mr Beckner was elected as the new chairman. Mr Ison was elected as the new vice chairman. For a complete list of Board members please click on www.dhp.virginia.gov/pharmacy/pharmacy_board.htm.

Entering License Renewal Period for 2007

Renewal notification letters will be mailed in mid November. This letter will state that you may now renew your license via the electronic renewal process on the Board's Web site. The letter will also contain a personal identification number (PIN), which may be used when renewing online. If you are accustomed to using a different PIN, you may continue to do so, or you may use the newly assigned PIN, which will override any PIN used in the past. As always, you are encouraged to renew online; however, instructions for obtaining a renewal form that may be mailed to the Board will be included on the notification letter.

The renewal fees are being reduced again this year to continue reducing a surplus in revenue. The renewal fees for this year will be as follows: pharmacist active license – $50; pharmacist inactive license – $25; pharmacy technician registration – $15; and pharmacy permit – $210.

In addition to submitting the renewal fee, each pharmacist or pharmacy technician must verify that he or she has successfully obtained all necessary continuing education (CE) hours during the 2006 calendar year. Pharmacists need 15 hours per calendar year and pharmacy technicians need five hours per calendar year for compliance. Please, make sure that you have obtained your required CE before renewing. Falsely certifying that you have obtained the required CE may result in disciplinary action by the Board. If you have not obtained your CE, you may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause only. Such a request must be made in writing and needs to be made before renewing your license. Be aware that any person who requests an extension will be audited the following year and will be required to submit original CE documents. For example, if you had requested an extension in 2005, you will be audited in 2007 and required to produce all CE hours required for the 2005 and 2006 renewal periods.

Also, all pharmacists-in-charge are responsible for ensuring that any pharmacist or pharmacy technician working in your pharmacy has a current and active license with the Board. Therefore, after December 31, 2006, please remember to verify that licenses have been renewed and are properly posted. For additional information related to CE, please refer to guidance documents 110-4 and 110-19 at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

Changes in Staff

As many may know, Robert C. "Bob" Stout retired earlier this year from the Virginia Department of Health Professions. Mr Stout most recently served as the pharmacy inspector for the southwestern region of the state. He had worked for the Department of Health Professions for almost 20 years and retired from the state with nearly 28 years of service. He has certainly been missed by staff and licensees, and the Board of Pharmacy extends its appreciation and gratitude to Mr Stout for his many years of public service.

Replacing Mr Stout is Toni Aust who accepted this position several months ago and has already proven to be a great asset. The Board welcomes Ms Aust to the agency and wishes her well. A complete list of staffing directories for the Board may be located at www.dhp.virginia.gov/pharmacy/pharmacy_staff.htm and for the Enforcement Division, which includes pharmacy inspectors at www.dhp.virginia.gov/Enforcement/enf_staff.htm.

Allowable Changes to a Schedule II Prescription

The Board is frequently asked to explain which information may be lawfully changed by the pharmacist on a Schedule II prescription. The answer found below was copied from the Questions & Answers section of the Drug Enforcement Administration's (DEA) Web site at the following link: www.deadiversion.usdoj.gov/faq/general.htm. Please review this site for other helpful information.

Continued on page 4

FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm.* October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical®, Micalcin®**) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP®**), sumatriptan (**Imitrex®**), and zolmitriptan (**Zomig®**).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register,* FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors™ accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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Question: What changes may a pharmacist make to a prescription written for a controlled substance?

Answer: The pharmacist may add the patient's address or change the patient's address upon verification. The pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted on the prescription as well as the patient's medical record. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance [CS] prescriptions. The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address, and such additions should be verified. The pharmacist is never permitted to make changes to the patient's name, [CS] prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

2007 Board Calendar

The 2007 dates for full Board meetings were recently scheduled and are as follows: March 28-29 (Board retreat and meeting), June 12, September 12, and December 12. Throughout the year, the Board calendar will be updated to include any changes of meeting dates and dates for various committee meetings as they are scheduled. These dates along with the minutes from each meeting may be accessed on the Web site at www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm.

Prescription Monitoring Program

Expansion update: Pharmacies and other dispensers have submitted over three million prescription records to the program database since the expansion date. One hundred twenty-four pharmacists and 264 prescribers have registered to use the program's Data Center to request patient specific information to assist them when dispensing or prescribing Schedule II, III, and IV drugs. Additionally, the program has processed over 2,200 requests for information since June 1, 2006, compared to 1,791 requests for all of 2005. For more information on how to register to use the program, please click on www.dhp.virginia.gov/dhp_programs/pmp/default.asp.

Important Information for Pharmacies Reporting Data

- All transactions for dispensing of Schedule II, III, and IV drugs must be submitted at least twice monthly. The deadline for reporting the dispensing data between the first and 15th of the month is the 25th of that month. The deadline for reporting the dispensing data between the 16th and the last day of the month is the 10th of the next month. Dispensers are encouraged to report prior to the deadline in order to have time to correct any rejected submissions. Dispensers who so choose may report more frequently than twice a month, eg, weekly or daily.
- The pharmacy's National Council for Prescription Drug Programs (NCPDP) number (formerly known as the National Association of Boards of Pharmacy® [NABP®] number) must be included when reporting prescription data. This is the way that pharmacies are identified in the database. Do not report using the pharmacy's DEA number or your report will not be associated with your pharmacy, ie, if a pharmacy reports using the pharmacy's DEA number, the pharmacy may receive a confirmation indicating a successful upload of the reporting data, but the database will not recognize that the pharmacy has reported. Subsequently, that pharmacy will be included on the report to the program showing non-reporting dispensers. If your pharmacy's software defaults to the DEA registration number when reporting, you must change this to the NCPDP number prior to uploading the data. If you are unsure how to change this setting in your software, please contact your software provider or the contractor responsible for data collection. Optimum Technology may be contacted at 866/683-2476 or via e-mail at varxreport@otech.com.
- A list of pharmacies that do not report is sent to the Virginia Department of Health Professions within two business days of the deadline for each reporting period. For those pharmacies or dispensers that appear on the non-reporting list, a notification letter will be sent from the Board requesting that the prescription data be sent immediately. If there is no response or an inadequate response, then a certified letter will be sent requesting the data. If an appropriate response is still not received by the Board, then the matter will be referred for disciplinary action to include, but not be limited to, the offering of a pre-hearing consent order requiring the immediate submission of the required data and a $1,000 fine for each unreported period.
- If a pharmacy does not dispense any Schedule II, III, or IV CS during a reporting period a "zero" report must also be submitted online. If a pharmacy never dispenses any Schedule II, III, and IV substances, it may request to be exempted from reporting. That form may be found on the Web site at www.dhp.virginia.gov/dhp_programs/pmp/pmp_forms.asp.

Use Caution When Therapeutically Substituting

It has come to the Board's attention that many pharmacy computer software programs link brand name drugs with generic drugs that are not necessarily approved by Food and Drug Administration (FDA) as being therapeutically equivalent. Pharmacists who substitute a drug with a product that is not therapeutically equivalent, or A-rated, as indicated in the "Orange Book" (published by FDA) are potentially dispensing the wrong drug product and violating §54.1-3408.03 of the Drug Control Act. In order to lawfully substitute a drug product that is not therapeutically equivalent, a pharmacist must first obtain permission from the prescriber. Pharmacists must ensure that all substitutions of a drug product comply with state law and must not simply rely on the information provided by the pharmacy's software.

For a listing of generic substitutions of commonly prescribed drugs and a brief explanation of the rating system used by the "Orange Book," please click on the following link to view an article recently published in the *Pharmacist's Letter:* www.pharmacistsletter.com/pl/220901.htm. Additionally, the electronic version of the "Orange Book" may be accessed at: www.fda.gov/cder/ob/default.htm. For instructions on how to use the "Orange Book" click on "FAQ" on the home page.

Revised Applications Posted to Web site

Please be aware that applications are occasionally amended as problems arise or when laws and regulations are changed. Most recently, the pharmacy technician application was amended to clarify the need for specific attachments and to create a user-friendly checklist for submitting the application. In addition, the wholesale distributor, warehouser, medical equipment supplier, and non-resident pharmacy applications have been amended due to recent regulatory changes.

Prior to submitting an application, always download the current application from the Board's Web site to ensure the submission of the appropriate application. Do not simply photocopy an application previously downloaded. Submitting an old application will result in the application being returned to the applicant thus delaying the licensure process. A list of all Board of Pharmacy applications may be found at www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm.

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